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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,931	12/31/2003	Dilip G. Saoji	U 013963-9	6678

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EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/749,931	SAOJI ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

In view of further consideration, the Final Rejection of November 8, 2005 is hereby withdrawn in order to introduce a new ground of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 45-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al (U.S. Patent No. 4,522,879) and de Souza et al (U.S. Patent No. 6,514,986) in view of Ishibashi et al (U.S. Patent No. 6,638,534) or Rubinfeld et al (U.S. patent No. 5,824,668).

Ishikawa et al disclose a composition comprising the claimed compound (column 25, lines 65-68 and column 26, lines 1-25) but do not disclose said compound in combination with an amino acid or cyclodextrin. However, since Ishibashi et al disclose that cyclodextrins and amino acids are well known solubilizing agents (column 11, lines

31-34) and Rubinfeld et al disclose a conventional use of cyclodextrins as solubilizing agents (column 2, lines 26-67, columns 3-4 and column 10, lines 27-40), a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to combine a compound disclosed by Ishikawa et al with a cyclodextrin or an amino acid in order to improve solubility of said compound.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45-82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12, 1, 18, 29 and 30 of U.S. Patent No. 6,514,986 in view of Ishibashi et al (U.S. Patent No. 6,638,534) or Rubinfeld et al (U.S. Patent No. 5,824,668). The claims of U.S. Patent read on compositions comprising the claimed compound but not in the combination with a solubilizing agent. However, since amino acids and cyclodextrins were well known in the art as solubilizing agents as disclosed by Ishibashi et al (column 11, lines 31-34) and Rubinfeld et al

(columns 2-4 and 10), a person having ordinary skill in the art at the time of the claimed invention would have been motivated to add amino acid or a cyclodextrin to the patented compositions in order to improve the solubility of the patented compound.

Claims 45-82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,608,078 in view of Ishibashi et al (U.S. Patent No. 6,638,534) or Rubinfeld et al (U.S. Patent No. 5,824,668). The patented claims read on compositions comprising the claimed compound but not in combination with a solubilizing agent. However, since each of Ishibashi et al and Rubinfeld et al disclose the conventional use of solubilizing agents as described above, the claimed compositions are prima facie obvious over the patented compositions.

Claims 45-82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 8-111 of U.S. Patent No. 6,664,267 in view of Ishibashi et al (U.S. Patent No. 6,638,534) or Rubinfeld et al (U.S. Patent No. 5,824,668) for the same reasons as set forth above.

Claims 45-82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims1-10 of U.S. Patent No. 6,750,224 in view of Ishibashi et al (U.S. Patent No. 6,638,534) or Rubinfeld et al (U.S. Patent No. 5,824,668) for the same reasonsas set forth above.

Claims 45-82 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6, 7, 21-23, 29-38 and 45-47 of copending Application No. 09/566,875 in view of Ishibashi et al (U.S. Patent No. 6,638,534) or Rubinfeld et al (U.S. Patent No. 5,824,668) for the same reasons as set forth above..

This is a provisional obviousness-type double patenting rejection.

Claim 67 is objected to because of the following informalities: claim 67 is a duplicate of claim 58. Appropriate correction is required.

Claims 1-58, 67-76, 81 and 82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims encompass a crystalline 0.2 hydrate compound in a solution. However, there is a good reason to doubt that a crystalline compound can retain its hydrate form in a solution.

Claims 69-80 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 69-80 are directed to the treatment of bacterial infection disease. Therefore, there is no antecedent basis in the preamble of the claims for the administration of a prophylactically effective dose as set forth in claim 69. It is not clear what is meant by "method composition" (claim 77).

Applicant's arguments filed May 8, 2006 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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PRIMARY EXAMINER
GROUP 1200